PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Bernard FROMENTY et al. Group Art Unit: 1611

Application No.: 10/553,807 Examiner: G. POLANSKY

Filed: February 2, 2006 Docket No.: 125649

For: METHOD FOR THE TREATMENT OF DISEASES LINKED TO AN ACCUMULATION OF TRIGLYCERIDES AND CHOLESTEROL

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the July 18, 2008 Restriction and Election of Species Requirement, the shortened statutory period for reply having been extended by the attached Petition for Extension of Time, Applicants provisionally elect Group I, claims 1, 3, 5-20, 22-28 and 37, and elect as a Species the following:

"obesity"

with traverse. At least claims 1, 3, 6, 8, 9, 14-20, 28 and 37 read on the elected species. At least claims 1, 6, 14-20 and 28 are generic.

National stage applications filed under 35 U.S.C. §371 are subject to unity of invention practice as set forth in PCT Rule 13, and are not subject to U.S. restriction practice. *See* MPEP §1893.03(d). PCT Rule 13.1 provides that an "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention may be apparent "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. *See* MPEP §1850(II), quoting *International Search and Preliminary Examination Guidelines* ("ISPE") 10.03. Lack of *a priori* unity of invention only exists if there is no subject matter common to all claims. *Id.* If *a priori* unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established *a posteriori* by showing that the common subject matter does not define a contribution over the prior art. *Id.* Furthermore, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims. *See* ISPE 10.06.

The Office Action acknowledges that *a priori* unity of invention exists because all claims include β-aminoisobutyric acid as common subject matter. See page 2. However, the common subject matter between the claims is not merely β-aminoisobutyric acid *per se*.

Rather, the common subject matter between the claims at least includes "β-aminoisobutyric acid as a therapeutically active agent" (or, similarly, in claim 35, "as [a] nutritional active agent"). Moreover, all independent claims except claims 21, 22 and 25 at least include β-aminoisobutyric acid in "an effective amount" (or, similarly, in claim 35, "in an efficient amount"). Furthermore, all independent method claims require "administering [β-aminoisobutyric acid] to a human or non human animal."

Thus, while the non-patent literature entitled "Occurrence of β-aminoisobutyric acid in Mytilus edulis" to Awapara et al. ("Awapara") discloses β-aminoisobutyric acid *per se*, Awapara does not disclose β-aminoisobutyric acid as a therapeutically active agent. Likewise, Awapara does not disclose β-aminoisobutyric acid in an effective amount or administering β-aminoisobutyric acid to a human or non-human animal. Thus, β-aminoisobutyric acid as a therapeutically active agent is a special technical feature common to all claims. β-aminoisobutyricin acid in an effective amount is a special technical feature common to all claims except claims 21, 22 and 25. The administration of β-aminoisobutyric acid to a human or non-human animal is a special technical feature common to all method claims. Accordingly, Applicants respectfully submit that the Office Action has failed to establish a *prima facie* lack of unity of invention.

Furthermore, a restriction between different embodiments (species) of an invention encompassed by a single independent claim is only proper under PCT Rule 13 if the claim recites distinct embodiments (such as a Markush group), and the Office Action establishes that the distinct embodiments share no common subject matter that defines a contribution over the prior art. *See* IPSE 10.09; MPEP §1850(II). No independent claim recites the distinct species that form the basis for the election of species requirement in the Office Action. Therefore, the Office Action fails to show any lack of unity of invention between the species and, thus, requiring restriction between species is clearly improper.

Reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

Respectfully submitted,

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WPB:MCB/jls

Attachment:
Petition for Extension of Time

Date: September 18, 2008

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